Oregon

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Mr. Robert Wyatt
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RE: (DRAFT) PCB in Breast Milk at Portland Harbor

Dear Messrs. Wyatt and McKenna:

This letter is intended to accompany EPA's memo titled, "Proposed Risk Assessment Approach for Evaluating Potential Risks From Consuming Breast Milk." Although a breast feeding exposure scenario was not included in the April 2004 Programmatic Work Plan for the Portland Harbor Site, the Lower Willamette Group committed to discuss potential exposures to fetuses and nursing mothers. EPA further identified breast feeding as an exposure pathway of concern in our December 2005 Identification of Round 3 Data Gaps memo. In EPA's January 15, 2008 comments on the Comprehensive Round 2 Site Summary and Data Gaps Report, EPA reiterated that the breast feeding exposure scenario should be included in the baseline risk assessment and further discussion was necessary. Toward that end, EPA requested assistance from the Environmental Health Assessment Program (EHAP, formerly SHINE) to develop recommendations on how to address the health risks for infants exposed to PCBs in breast milk in the context of the many health benefits of breast feeding.

Background

Resident fish species collected within Portland Harbor have been found to contain levels of polychlorinated biphenyls (PCBs) that may pose a risk to human health. For example PCB levels of up to 4.5 and 6.5 mg/kg have been detected in smallmouth bass tissue and carp tissue samples collected from Portland Harbor respectively. Consuming resident fish species from the harbor has been declared a public health hazard, and correlated fish advisories have been issued[1]. The current fish advisory includes the following clause: "Women of childbearing age, especially women who are pregnant, thinking about getting pregnant or nursing, infants and children and people with weak immune systems, thyroid or liver problems, should avoid eating resident fish from Portland Harbor. Examples of resident fish include bass, carp and bullhead catfish."[1]

Despite the current advisory, subsistence fishing from the harbor may occur, although the extent to which it occurs is unknown. The PCB content of breast milk is closely related to the concentration of PCBs in the adipose tissue of the mother. A mother eating resident fish species from Portland Harbor over a period of time would be expected to accumulate a significant amount of PCBs in her adipose tissue. Therefore, it is plausible to assume that an infant consuming the breast milk of a mother who has a significant body burden of PCBs could receive a relatively high dose of PCBs.

The breast feeding exposure pathway for environmental contaminants presents unique challenges to the health/risk assessor and public health officials. In most health/risk assessments, the exposure medium is considered only a delivery vehicle for the contaminant of concern. In the case of breast milk, however, the exposure medium contains a multitude of healthful compounds that have been well documented to produce measurable health benefits. In fact, not breast feeding is considered a risk factor for several acute and chronic health conditions. Therefore, treatment of this exposure pathway requires not a simple assessment of risk, but rather, a balancing of the risks associated with contaminant exposure against the well documented health benefits of breast feeding. To further complicate this process, there is no accepted threshold value for PCBs in breast milk. In the absence of such thresholds, local, state, and federal health agencies struggle to formulate an appropriate public health response to this potential threat.

Discussion

Health benefits of breast feeding-

Breast feeding has been shown to be the healthiest option for infants under most conditions. Breast milk is an inexpensive, ideally balanced source of nutrition[2]. The infant immune system is matured and bolstered by breast milk components. Immunoglobulin A (IgA) in breast milk reduces the uptake of dietary antigens, protecting against development of food allergies[3]. IgA in breast milk also protects the infant against microbes from the maternal gut and prevents microbes from binding to the intestinal mucosal surface[4]. Breast milk also has anti-inflammatory properties, stimulates maturation of the intestinal epithelium and enhances the protective character of the intestinal mucosa[5]. This overall enhancement of immune function means reduced risk of multiple types of infectious disease for the infant.

Breast feeding is also associated with reduced risk of SIDS, type I and type II diabetes, leukemia, obesity, asthma, and high cholesterol[2]. Recent research suggests that exclusive breast feeding may reduce the risk of celiac disease[6]. There are also psychological benefits to the improved mother-infant bonding that accompanies consistent breast feeding. Overall, non-breast-fed babies have a 21 percent higher mortality rate than breast-fed babies[2].

Mothers who breast feed also enjoy health benefits including reduced postpartum bleeding, reduced risk of breast and ovarian cancer, easier loss of excess adipose accumulated during pregnancy, and enhanced psychological well-being with increased bonding between mother and child. Breast feeding also benefits society by reducing health care costs (healthier babies), increasing worker productivity (children sick less often), and introduces less waste into the environment[2].

PCBs in breast milk and children's health

Background concentrations of PCBs in breast milk vary by region and culture, but overall, these concentrations appear to be decreasing over time. The Agency of Toxic Substances and Disease Registry (ATSDR) suggests that 0.247 µg PCB/g-lipid might be the best current estimate.[7] PCB concentrations as high as 10-15 µg/g-lipid have been reported in instances where mothers were occupationally exposed[8]. People who consume large amounts of PCB-contaminated fish have also been shown to have higher breast milk PCB concentrations.[7] Studies found a negative correlation between PCB concentrations in the breast milk of nursing mothers and the health of their children. The adverse health effects in children associated with increasing concentrations of PCBs in their mothers' breast milk included deficits in neurobehavioral function, alterations within the immune system, and altered thyroid function (see table 1).[7]

One study, known as the "Dutch PCB/Dioxin Study," compared the neurological performance of children exposed to PCBs only prenatally with that of children exposed prenatally and postnatally via breast milk. While children consuming milk containing higher PCBs fared worse than children consuming milk with lower levels, all groups of breast-fed children fared better than bottle-fed children. [9,10] While this finding may have been confounded by socioeconomic status (women were offered free formula for participation in the study), authors concluded that breast feeding, even with PCB-contaminated milk, served to counter the negative effects of prenatal PCB exposure[9,10]. The studies cited in this report conclude that, even at the highest breast milk PCB levels measured, the health benefits of breast feeding still outweigh the risks associated with contaminant exposure.

The highest PCB concentration measured in breast milk that EHAP was able to find in the literature was 15 µg/g-lipid. While this study by Hara[8] identified more health effects in children who breast-fed for more than 5 months from mothers with extensive occupational PCB exposure histories, these effects were self-reported, and none of the children were diagnosed as having PCB poisoning by health care professionals. An additional limitation of this study is that health effects were compared based on the mothers' occupational exposure history rather than on breast milk PCB concentrations.

How does the estimated PCB dose to infants via breast milk compare with dose responses observed in animal studies?

The doses of PCBs that a breastfeeding infant may be expected to receive, given breast milk PCB concentrations measured in the literature, are presented in table 1 (see appendix A for calculations and exposure assumptions). These doses range from 0.0011 to 0.0048 mg/kg/day and are 36-160 times higher than ATSDR's minimal risk level (0.00003 mg/kg/day) for PCB exposures that last between 15 and 364 days. These doses are slightly lower than that shown to cause health effects in monkeys (0.005 mg/kg/day). Health effects that occurred in monkeys at 0.005 mg/kg/day include altered finger and toe nails and nail beds, inflammation of eye-lid glands, and decreased immunity.[7]

Risk vs. Benefit-

If a PCB dose of 0.001 mg/kg/day were estimated in any other media, EHAP would recommend that citizens reduce or eliminate their exposure to that medium. However, PCB exposure via breast milk necessarily follows additional prenatal exposures during critical developmental windows. Studies cited here suggest that breast milk, even with significant PCB contamination, may serve to reverse or stabilize developmental lesions initiated by prenatal exposure[9,10].

To date there has been no biomonitoring to determine the breast milk PCB concentrations of women who consume fish from Portland Harbor. However, tissue PCB concentrations in the fish from Portland harbor have been measured. PCB contamination in Portland Harbor fish is similar to that found in fish at other sites where corresponding breast milk concentrations have been found to be elevated.[7]

The primary goal for environmental and health agencies should be to reduce PCB exposure to women of childbearing age. As PCB-contaminated fish can be a major source of maternal PCB body burdens, these findings reinforce the importance of the current fish advisory for Portland Harbor issued by Oregon's Office of Environmental Public Health (OEPH)[1]. However, the recommended course for infants who have already had prenatal exposure to PCBs is clear. Breast feeding is best for infants regardless of PCB levels in the milk.

Affected population and EHAP activities-

In regards to the Portland Harbor Superfund site, the affected population (subsistence fish eaters who are pregnant, planning on becoming pregnant or nursing) includes hard-to-reach ethnic communities. Since 2002, EHAP has worked with community-based organizations and local agencies to identify affected populations and provide information to them about safe fish consumption.

Conclusions

-For lipophilic environmental contaminants such as PCBs, the nursing infant receives the highest dose of contaminant and is the population most sensitive to that contaminant.

-Breast milk containing high background PCB concentrations could result in doses to infants as much as 160 times higher than ATSDR's Minimal Risk Level for PCBs but are below the levels where adverse health effects have been seen in humans. However, due to the significant benefits of breast milk, breast feeding should still be recommended. Studies cited here suggest that breast milk, even with significant PCB contamination, may serve to reverse or stabilize developmental lesions initiated by prenatal exposure. EHAP concludes that PCB contaminated breast milk poses **no apparent public health hazard**.

-Elevated levels of PCBs in breast milk indicate significant prenatal exposure to PCBs.

-Eating resident fish species from Portland Harbor remains a **public health hazard** for nursing and pregnant women. The current fish advisory is protective of nursing infants as long as their mothers adhere to it. (See current advisory at: http://www.oregon.gov/DHS/ph/envtox/fishconsumption.shtml#Portland)

-Data gaps about actual exposure and resulting body burdens from these contaminants at Portland Harbor exist. Biological monitoring of breast milk from women who eat fish from Portland Harbor would help to fill this data gap.

-Because remediation will not likely reduce PCB levels below health-based guidelines for several decades, effective risk mitigation depends on adherence to current fish advisories. Lack of resources for community outreach and education regarding fish advisories limits the effectiveness of those advisories to protect public health.

Recommendations

- A sustained community outreach campaign directed towards women of childbearing age who are high fish consumers is necessary and should be included as part of the site remedy. Given the health risks associated with PCB exposure to pregnant and nursing mothers, EHAP recommends that the LWG not delay implementation of this community outreach program. Further discussion is required to determine how to best implement this community outreach campaign prior to the selection of a site remedy. This campaign should promote breast feeding as the healthiest option for infants regardless of the mother's exposure scenario, promote fish as a healthy source of nutrition, but discourage eating resident fish species from Portland Harbor such as bass, carp, and catfish. To effectively encourage these health-protective behaviors, the outreach campaign should:

- Identify affected populations (i.e., ethnic or cultural groups that report frequent consumption of locally caught fish)
- Characterize affected populations as to:
    - Effective communication channels
    - Beliefs, attitudes, and knowledge about breast feeding and environmental contaminants in the fish they consume
    - Fishing practices (species and parts of fish consumed, locations fished, frequency, preparation methods)
- Develop culturally appropriate strategies and messages to encourage desired behaviors in target populations
- Implement the strategies and disseminate the messages that have been developed in the manner determined to be most effective for target populations
- Evaluate effectiveness of the campaign by assessing behavior changes in target populations

-EPA and LWG should include language in the baseline human health risk assessment encouraging women to continue breast feeding regardless of contaminant exposure. This language should include information on the well-documented health benefits of breast feeding.

-EHAP strenuously encourages all women of childbearing age to abide by the current fish advisories for Portland Harbor by avoiding resident fish species from Portland Harbor. (See current advisory at: http://www.oregon.gov/DHS/ph/envtox/fishconsumption.shtml#Portland)

-EHAP recommends that all women continue to breastfeed their infants regardless of exposure situation unless directed otherwise by their physician.

Table 1[a]
Health Effects in Human Infants Associated with PCBs in Breast Milk

Study	Mean Breast Milk PCB Conc. (µg/g-lipid)	$ADD_{nc\text{-}infant}$[b] (mg/kg/day)	Observed Health Effects[c]
Michigan Cohort	0.87 (fisheaters) 0.62 (nonfisheaters) Total PCBs	0.0023 (fisheaters) 0.0016 (nonfisheaters)	Reduced birth weight, head circumference, and gestational age in newborns. Neurobehavioral alterations in newborn and older children.
Dutch Cohort	0.62 Total PCBs	0.0016	Reduced birth weight. Reduced growth during first 3 months in formula-fed, but not breast-fed children. Neurobehavioral alterations and changes in T-lymphocyte subpopulations and thyroid hormone levels in infants.
German Cohort	0.43 Sum of PCB congeners[d]	0.0011	Neurodevelopmental and thyroid hormone alterations in infants.
Inuit Infant Study	0.62 Sum of PCB congeners[d]	0.0016	Immunologic alterations.
North Carolina Cohort	1.8 Sum of PCB congeners[d]	0.0048	Neurobehavioral alterations in infants
	Intermediate-duration MRL[e] for Aroclor 1254:	**0.00003 mg/kg/day**	

Notes:

- **a)** Adapted from Table A-1 in ATSDR's Toxicological Profile for PCBs[7]
- **b)** Non-cancer Average Daily Dose to infant via breast milk. Parameter not reported in studies, but doses were calculated for infants nursing from mothers with mean breast milk PCB concentrations reported. This exposure pathway is not applicable to formula-fed infants. (See Appendix A for calculations and assumptions). It is important to note that any exposure via breast milk follows an unquantified prenatal exposure.
- **c)** No distinction between effects due to prenatal exposure and effects due to postnatal exposure via breast milk (unless otherwise noted in table).
- **d)** PCB value is the sum of three non-dioxin-like congeners (PCB 138, PCB 153, and PCB 180).
- **e)** MRL = minimal risk level for intermediate-duration exposure (two weeks to one year).

Sincerely

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[2] Department of Health and Human Services, National Women's Health Information Center (2008) website http://www.4women.gov/breastfeeding/index.cfm?page=227

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